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16

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1. The present invention relates to a method of...

2. The present invention relates to a method of...

3.

4. The present invention relates to a method of...

5. The present invention relates to a method of...

EXAMINER
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ART UNIT	PAPER NUMBER
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13

DATE MAILED:

05/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Applicati n No.

08/878,177

Applicant(s)

IWAMOTO ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 20, 26-32 is/are rejected.
- 7) ☐ Claim(s) 21, 25 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: .

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This Office Action is in response to Paper #12, filed November 16, 1999. Claims 1 and 3-19 have been cancelled. Claims 2 and 20-33 are currently pending.

Newly submitted claims 22-24 and 33 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The nucleic acid encoding C-11 protein, vectors, hosts, methods of making the protein is patentably distinct from a method of expressing an antisense nucleic acid because the methods and endpoints are wholly different. This nucleic acid is also distinct from probes of Claim 22 because one results in the expression of a protein and the other for the amplification of nucleic acid.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-24 and 33 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 2, 20, 21, 25-32 are currently under examination.

#### **Maintenance of Rejections/Inclusion of Newly Added Claims**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2, 20, 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhordain et al. (1995; Mechanisms of Development 50:117-28). Dhordain et al. teaches the cDNA encoding c-erg. C-erg lacks amino acids 197-221 and 223-225 in the amino acid sequence depicted in SEQ ID NO:2 (C-11 protein). Further, this c-erg is shown in the specification to have calcification inhibitory activity. C-erg is a transcriptional activator as noted in the Dhordain et al. abstract and has the ability to upregulate the activity of a wide range of gene promoters or

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enhancers (page 18, col. 1, para. 1). Therefore, c-erg increases the DNA synthesizing ability of cells. Therefore, the cDNA encoding c-erg anticipates the gene encoding the protein of Claim 2.

The cDNA encoding c-erg is identical to SEQ ID NO:4 except through amino acids 381-421 wherein amino acids are substituted, deleted, or inserted. As noted above, c-erg is shown in the specification to have calcification inhibitory activity. C-erg is a transcriptional activator and has the ability to upregulate the activity of a wide range of gene promoters or enhancers. Therefore, Claim 20 is anticipated by Dhordain et al.

The cDNA encoding c-erg was placed into pLC24 (Claims 26, 27) and expressed from bacteria (Claims 28-30) – see page 27, col. 1, para. 4. The cDNA encoding c-erg was placed into pSG5<sup>ck-erg</sup> (Claims 26, 27) and expressed in eukaryotic NIH3T3 cells (Claims 28-31) – see page 27, col. 1, para. 5. Total cell extracts were prepared (Claim 32) – see page 27, col. 1, para. 5).

Claims 21 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Response to Arguments**

Applicants urge that Dhordain et al. do not anticipate the claims because Dhordain et al. do not teach that c-erg possesses increased DNA synthesizing ability. Indeed, c-erg is taught in Dhordain to be a transcriptional activator, and therefore has DNA synthesizing ability. This argument is not persuasive.

Additionally, Applicants comment that C-11 lacks specific amino acids and not c-erg. The examiner's sequence search shows the sequences as stated above. In either event, the art is applied the same.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

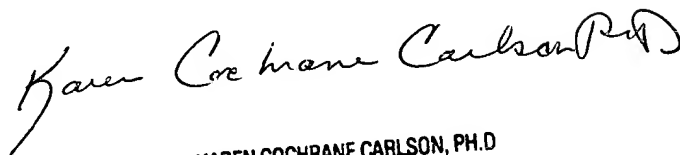
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:30 AM - 5:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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September 19, 2000



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER